

Disposable Lyophilization Tray

Disposable Lyotray is a new type of disposable lyophilization tray developed based on the use scenario of traditional lyophilizer and lyophilizer process.



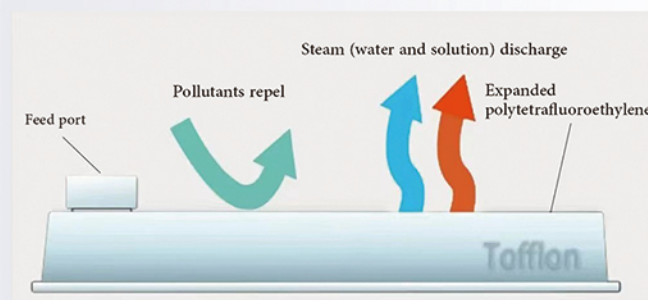
The use method is consistent with the traditional tray, compatible with most freeze-drying process, can greatly save cleaning time verification cost thin and unique material with strong air permeability, so that the sample and the plate layer contact is good, heat transfer is uniform, effectively optimize the freeze-drying process, improve the work efficiency of the freeze-drying plate design into a disposable container, using the principle of E-PTFE film Not only can have good asepsis guarantee, but also can effectively prevent the product from flying, improve the product yield, widely used in high-end freeze-dried products.

Typical Application

Development of freeze-drying process for Bio-pharmaceutical peptides\Oligonucleotides\Proteins\Pharmaceutical intermediates, polysaccharide strains and other apis for clinical staging and large-scale production.

Main Features and Advantages

- ◆ Convenience - The use method is as convenient as the traditional tray, which saves the time of cleaning the tray and saves the verification and labor cost, so as to improve the work efficiency. There is no metal particles during sampling, and it is easy to discard after taking the medicine
- ◆ Space saving - aseptic closed system to facilitate liquid storage and reduce storage space
- ◆ High efficiency -the product is close to the shelf, effectively overcome the splash phenomenon in the freeze-drying process and reduce waste
- ◆ Quality lyophilization-lyophilization tray is light and thin with strong air permeability. The flexible bottom film is adopted to make the tray frame heat transfer evenly, effectively optimize the freeze-drying effect and heat transfer evenly,Ensure product consistency
- ◆ Personnel safety - no dust emission
- ◆ Stability - the material has good stability



Production Environment and Quality Control

Products are manufactured, assembled and packaged in clean rooms
Clean room meets GMP grade C standard
The quality management system has passed ISO 9001 system certification
Products through strict light table inspection, to ensure the qualified rate of 99.99%

Product Standards Meet The Following Requirements

Biocompatibility	USP < 88 > in vivo biological reactivity test, USP < 87 > in vitro biological reactivity test
Bacterial endotoxin	Chinese Pharmacopoeia Part IV 1143 bacterial endotoxin test method 1 gel method
Physical Chemistry	The experiment of physical and chemical container test complies with USP < 661 > in the part of test method and expanded extract (solvent), physical and chemical test
Insoluble particles	Chinese Pharmacopoeia Part IV 0903 insoluble particle examination method 1 photoresist method
Sterility test	Sterility test method 1101, Part IV of Chinese Pharmacopoeia
No animal origin ingredients	TSEBSE certificate

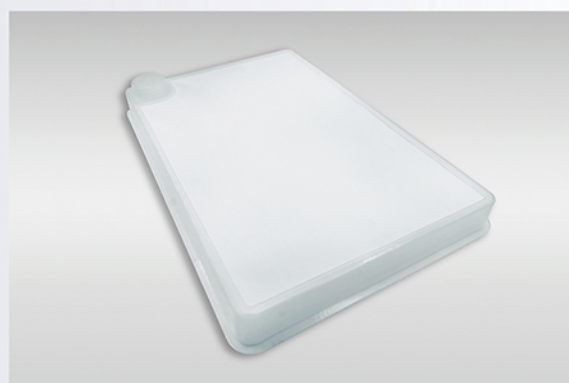
*See validation guide for details

Technical Parameter

- Product size: 398*270*48mm
- Product specification: 1.8 L
- Recommended capacity: 200-1800 ml
- Service temperature: (-80)°C~(+125)°C
- Packing: Double pack 10 PCS per carton
- Sterilization method: Irradiation sterilization
- Main product: Medical grade polypropylene (PP)
- Bacteria-blocking breathable membrane: Medical-grade expanded polytetrafluoroethylene (E-PTFE)
- Aperture: 0.22 μ m
- Bottom film: Medical grade polypropylene(PP)

Storage Conditions

- Recommended storage temperature range: room temperature
- Recommended range of storage humidity: <65%
- Warranty period :2 years



Operating Instructions

▪ Unpacking of Disposable Lyophilization Tray:

When opening the outer packing box, be careful to gently cut the outer packing box with a sharp tool to avoid scratching the product or damaging the sterility of the product in the inner packing; Open the inner packaging bag in the area with the same cleanliness level as the product and take out the lyophilization tray. When taking out, grasp the side skeleton of the tray and pull it out slowly to avoid damage to the respiratory membrane and the bottom of the tray by fingertips and nails.

▪ Filling Instructions:

1. Place the lyophilization tray on a flat surface.
2. Unscrew the valve cover from the injection port.
3. Inject the appropriate volume of product into the container according to the aseptic operation process; Injection volume ≤ 1.8 L
4. Put the valve cover of the injection port back to the upper part of the injection port and tighten it by hand.
5. Place the lyophilization tray in the lyophilizer chamber for freeze-drying.

▪ Product Collection:

1. Take out the lyophilization tray and turn it upside down.
2. Use a sharp tool to scribe the bottom of the flexible film along a corner. Be careful not to cut into the body. The lyophilization tray is supported by the scratch free corner and tray, and the dry powder is poured into the collection bag or mixing device through the scratch corner. The materials attached near the freeze-dried film can be scraped slightly with soft objects. Do not use sharp tools to scrape the materials adhered to the film, so as to prevent the film from falling off and entering the product.

